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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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John Hatlestad

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EXAMINER

RANGREJ, SHEETAL

ART UNIT

PAPER NUMBER

3626

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/787,045	Applicant(s) HATLESTAD ET AL.	
	Examiner SHEETAL R. RANGREJ	Art Unit 3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 and 16-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 March 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Prosecution History Summary

- Claim 15 is cancelled.
- Claims 1-2, 4, 8-9, 11, 16-18, 21, 24-28 are amended.
- Claims 1-14 and 16-28 are pending.

DETAILED ACTION

Response to Amendment

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 03/14/2008 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of **, based on the logic and sound scientific reasoning of one of ordinary skill in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (mailed: 10/09/2007).

Drawings

1. The drawings were received on 03/14/2008. These drawings are accepted.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 9-14 and 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Yarin et al. (U.S. Patent No. 6,294,999).

4. As per claim 9, Yarin teaches an electronic patient health management system, comprising:

-a medical measurement device for measuring data related to at least one patient physiological

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health factor including fluid retention data (**Yarin: col. 5, 49-64**);

-a medication therapy management device, configured to house diuretic medication and store data related to patient consumption of medication (**Yarin: col. 3, 37-40**), the medication therapy management device further configured for interrogating the medical measurement device and processing the data retrieved from the medical measurement[[s]] device and the data related to patient consumption of medication (**Yarin: col. 11, 5-10; col. 11, 34-47**); and

-a patient wellness host system, communicatively coupled to the medication therapy management diagnostic device, configured to receive and display the processed data (**Yarin: col. 11, 20-23**) and use the processed data to generate a diuretic medication therapy regimen (**Yarin: figure 8**).

5. As per claim 10, Yarin teaches wherein the medication therapy management diagnostic device is further configured to provide a reminder to a patient when it is time to take the medication (**Yarin: col. 10, 63-64**).

6. As per claim 11, Yarin teaches wherein the medical measurement device is an external measurement device (**Yarin: col. 11, col. 3, 51-65**).

7. As per claim 12, Yarin teaches wherein the medical measurement device is an implantable device (**Yarin: col. 11, col. 3, 51-65**). The examiner interprets that the invention does not change as a whole because data is communicated with a device; the invention as a whole doesn't change with the device being an external device or an implantable device.

8. As per claim 13, Yarin teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via an Internet connection (**Yarin: col. 3, 41-50**).

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9. As per claim 14, Yarin teaches wherein the medical measurement electronic diagnostic device is communicatively coupled to the patient wellness host system via a wireless communication link (**Yarin: col. 3, 41-50; col. 6, 3-5**).
10. As per claim 16, Yarin teaches wherein data related to the at least one patient physiological health factor comprises data monitored by an implantable device (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**).
11. As per claim 17, Yarin teaches wherein data related to the at least one patient physiological health factor comprises weight data (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**).
12. As per claim 18, Yarin teaches wherein data related to the at least one patient physiological health factor comprises neuro-hormonal data (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**).
13. As per claim 19, Yarin teaches wherein data related to the at least one patient physiological health factor comprises renal function data (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**).
14. As per claim 20, Yarin teaches further configured to process said data received in order to develop and display a therapeutic response (**Yarin: col. 11, 11-26**).
15. As per claim 21, Yarin teaches wherein the developed therapeutic response comprises revising medication regime (**Yarin: col. 11, 48-54**), maintaining current medication regime (**Yarin: col. 3, 36-40**), and recommending a diet plan (**Yarin: col. 11, 40-47**).
16. As per claim 22, Yarin teaches wherein the patient wellness host system is a computer, which comprises with a memory (**Yarin: col. 7, 3-5**), a processor (**Yarin: col. 6, 45-48**) and a user interface (**Yarin: col. 6, 26-28**).

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17. As per claim 23, Yarin teaches wherein the medication diagnostic device communicates with the patient wellness host system to alert the wellness manager that the medication level is below a pre-determined level (**Yarin: col. 5, 42-46**).

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1-8 and 24-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yarin et al (U.S. Patent No. 6,294,999) in view of Ellinwood, Jr. (U.S. Patent No. 3,923,060).

20. As per claim 1, Yarin teaches a medication storage, therapy, and consumption management system, comprising:

- a containment unit configured to accessibly house diuretic medication (**Yarin: figure 3**);
- a health management host system coupled to the containment unit in a manner that allows data transmission (**Yarin: figure 9**);
- said containment unit including communications and control system that records and transmits data relating to a medication event, said containment unit control system further providing for transmitting and receiving medication therapy data (**Yarin: figure 9**);
- said health management host system configured to receive data related to the medication event (**Yarin: col. 10, 53-62**), receive physiologic data (**Yarin: col. 9, 56-62**), analyze, and display the patient physiologic data and the medication event data on a health

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management display (**Yarin: col. 11, 27-32**), and generate a diuretic medication therapy regimen using the analysis of the patient physiological data and the medication event data (**Yarin: col. 12, 11-20**).

Yarin, however, fails to expressly teach a medication storage, therapy, and consumption management system, comprising: an implantable device configured to monitor fluid retention; and receiving patient physiological data including fluid retention data collected by the implantable device.

Nevertheless, these features are old and well known in the art as evidenced by Ellinwood. In particular, Ellinwood teaches a medication storage, therapy, and consumption management system, comprising: an implantable device configured to monitor fluid retention (**Ellinwood: col. 9, 20-34**); and receiving patient physiological data including fluid retention data collected by the implantable device (**Ellinwood: figure 4**).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Yarin with the teachings of Ellinwood with the motivation to provide a self-powered medication dispensing apparatus whose operation is made dependent on evaluation of changes in the sensed data (**Ellinwood: col. 2, 44-59**).

21. As per claim 2, Yarin teaches wherein the patient physiological data comprises weight, fluid retention data, data monitored by an implantable device and neuro-hormonal data (**Yarin: fig. 8; col. 5, 49-64; col. 6, 35-44**). The examiner interprets that measurements relating to weight, fluid retention data, data monitored by an implantable device, and neuro-hormonal data are included in the data gathered by various appliances.

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22. As per claim 3, Yarin teaches wherein the containment unit is further configured to communicate wirelessly with said health management host system (**Yarin: figures 1-2**).
23. As per claim 4, Yarin teaches wherein the containment unit is configured with a display device to illustrate a medication therapy strategy (**Yarin: fig. 12; col. 6, 29-35**).
24. As per claim 5, Yarin teaches wherein the containment unit is configured to receive data from an external source and further configured to transmit such data to the health management host system (**Yarin: col. 11, 28-33**).
25. As per claim 6, Yarin teaches wherein the containment unit is further configured to notify the patient when it is time to take the medication housed therein (**Yarin: col. 10, 63-64**).
26. As per claim 7, Yarin teaches wherein the containment unit is further configured to communicate a request for a medication re-fill with a pharmacy system when the quantity of the medication is below a pre-determined level (**Yarin: col. 3, 41-50**).
27. As per claim 8, Yarin teaches wherein said health management host system processes said data related to the medication event data and said patient physiological data, and in response thereto provides for the generation of an updated medication therapy regimen (**Yarin: col. 11, 11-26**).
28. As per claim 24, Yarin teaches a method for remote management of a medication therapy using a medication containment unit, the method comprising:
- alerting a patient when it is time to carry out diuretic medication step of a first therapeutic plan (**Yarin: col. 10, 53-64**);
 - sensing when the medication containment unit is engaged and recording the same as a medication event (**Yarin: col. 9, 21-41; col. 11, 5-10**);

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- receiving patient physiological data (**Yarin: col. 5, 49-54**);
- processing said patient physiological data and said medication event data (**Yarin: col. 11, 34-47**); and
- generating a second therapeutic plan in response to said processing of said patient physiological data and said medication event data (**Yarin: col. 11, 34-47**).

Yarin, however, fails to expressly teach a method for remote management of a medication therapy using a medication containment unit, the method comprising: implantably sensing fluid retention data; and receiving patient physiological data including the implantably-sensed fluid retention data.

Although Yarin teaches sensing fluid retention data (**Yarin: col. 5, 49-64**) and receiving patient physiological data (**Yarin: col. 5, 49-54**), it does not teach to sense it implantably. Nevertheless, these features are old and well known in the art as evidenced by Ellinwood. In particular, Ellinwood teaches a method for remote management of a medication therapy using a medication containment unit, the method comprising: implantably sensing fluid retention data (**Ellinwood: col. 9, 20-34**); and receiving patient physiological data including the implantably-sensed fluid retention data (**Ellinwood: figure 4**).

One of ordinary skill in the art would have found it obvious at the time of the invention to combine the teachings of Yarin with the teachings of Ellinwood with the motivation to provide a self-powered medication dispensing apparatus whose operation is made dependent on evaluation of changes in the sensed data (**Ellinwood: col. 2, 44-59**).

29. As per claim 25, Yarin teaches wherein the alerting step comprises notifying the patient consume at least one of medication (**Yarin: col. 10, 53-64**).

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30. As per claim 26, Yarin teaches wherein the alerting step comprises causing the medication containment unit to generate one of the following, an audible sound, to vibrate and to communicate with a second external device which responsively prompts the patient to act **(Yarin: col. 8, 43-48)**.

31. As per claim 27, Yarin teaches wherein the receiving step is initiated by an external device transmitting patient physiological data to the containment unit **(Yarin: col. 5, 49-54)**.

32. As per claim 28, Yarin teaches wherein the receiving step is initiated when the containment unit interrogates an external device **(Yarin: col. 5, 49-54)**.

Response to Arguments

33. Applicant's arguments with respect to claims 1-8 and 24-28 have been considered but are moot in view of the new ground(s) of rejection.

34. Applicant's arguments filed for claims 9-14 and 16-23 have been fully considered but they are not persuasive.

35. Applicant argues that Yarin et al. does not teach a medical measurement device that measures fluid retention data. Examiner disagrees. Yarin teaches Smart Tray (i.e. medication therapy management device) communicating with various appliances (i.e. medical measurement device) including but not ***limited to***...weight scales...(i.e. fluid retention data).

Conclusion

36. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

-Aten et al. (U.S. Patent No. 4,674,652) discloses a drug dispensing device that is controlled for the patient for a drug therapy.

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- Shepherd et al. (U.S. Patent No. 4,911,327) discloses a dispenser for providing scheduled dosages of pills according to a predetermined medication program.
- Fearnot (U.S. Patent No. 5,040,533) discloses an implantable container for housing a cardiovascular treatment device with an external window for sensing a physiological parameter.
- Drinan et al. (U.S. Publication No. 2003/0004403) discloses an invention that relates to methods and devices for remote or distributed continuous monitoring physiological parameters.
- Kehr et al. (U.S. Publication No. 2003/0036683) discloses a method and an apparatus used in remotely modifying medical protocols.
- Mann et al. (U.S. Publication No. 2004/0147969) discloses an apparatus for treating cardiovascular disease with an implantable device.
- Surwit et al. (U.S. Patent No. 6,980,958) discloses an apparatus configured to receive and analyze information regarding patient compliance with medication and alter treatment regimens based on that information.
- Ami J. Claxton, Joyce Cramer, Courtney Pierce, A systematic review of the associations between dose regimens and medication compliance, Clinical Therapeutics Volume 23, Issue 8, August 2001, Pages 1296-1310.

37. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571)270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Robert Morgan/
Primary Examiner, Art Unit 3626